

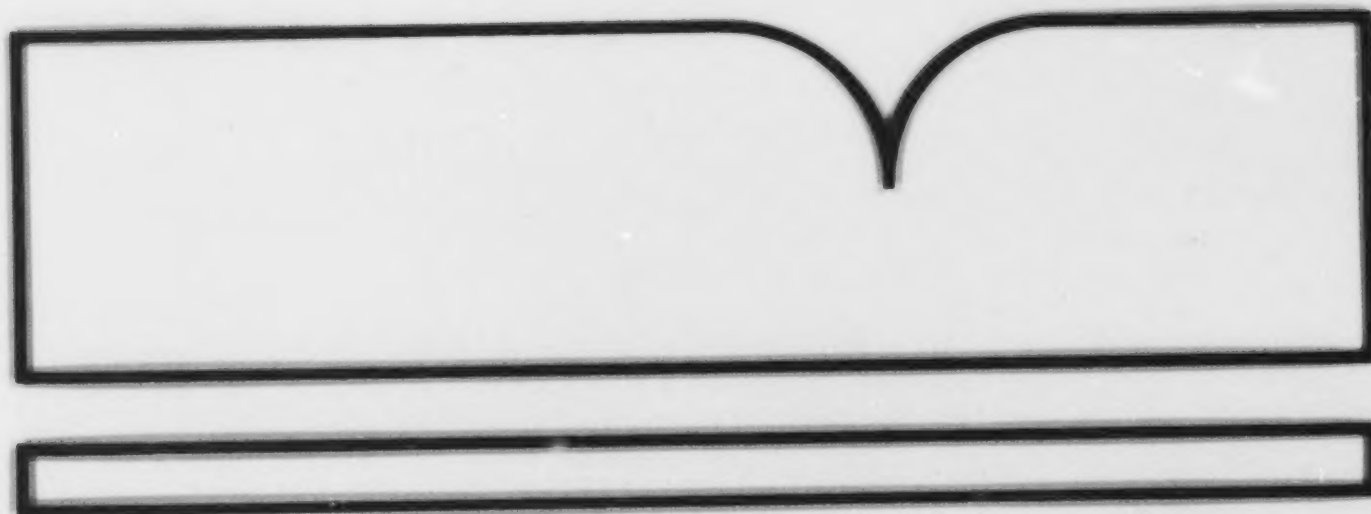
Laboratory and Field Audits as Part of the
EPA (Environmental Protection Agency)
Hazardous Waste Engineering Research Laboratory
(HWERL) Quality Assurance Program

S-Cubed, La Jolla, CA

Prepared for

Environmental Protection Agency, Cincinnati, OH

Jan 88



U.S. Department of Commerce
National Technical Information Service



EPA/600/D-88/014
January 1988

LABORATORY & FIELD AUDITS AS PART OF THE
EPA HAZARDOUS WASTE ENGINEERING RESEARCH
LABORATORY (HWERL) QUALITY ASSURANCE PROGRAM

By

W. Burton Blackburn
S-Cubed Division of Maxwell Laboratories
La Jolla, CA 92038-1620

Guy F. Simes
Hazardous Waste Engineering Research Laboratory
U.S. Environmental Protection Agency
Cincinnati, OH 45268

EPA Contract 68-03-4001

EPA Project Officer
Guy F. Simes

HAZARDOUS WASTE ENGINEERING RESEARCH LABORATORY
OFFICE OF RESEARCH AND DEVELOPMENT
U.S. ENVIRONMENTAL PROTECTION AGENCY
Cincinnati, OH 45268

TECHNICAL REPORT DATA		
(Please read Instructions on the reverse before completing)		
1. REPORT NO. EPA/600/D-88/014	2.	3. RECIPIENT'S ACCESSION NO. PB88-160288
4. TITLE AND SUBTITLE LABORATORY AND FIELD AUDITS AS PART OF THE EPA HAZARDOUS WASTE ENGINEERING RESEARCH LABORATORY (HWERL) QUALITY ASSURANCE PROGRAM		5. REPORT DATE January 1988
7. AUTHOR(S) W. Burton Blackburn Guy F. Simes		6. PERFORMING ORGANIZATION CODE
9. PERFORMING ORGANIZATION NAME AND ADDRESS S-CUBED Hazardous Waste Engineering LaJolla, CA 92038-1620 Research Laboratory 26 W. St. Clair St. Cincinnati, OH 45268		8. PERFORMING ORGANIZATION REPORT NO.
12. SPONSORING AGENCY NAME AND ADDRESS Hazardous Waste Engineering Research Laboratory Office of Research and Development U.S. Environmental Protection Agency Cinti, Oh 45268		10. PROGRAM ELEMENT NO.
		11. CONTRACT/GRANT NO. 68-03-4001
		13. TYPE OF REPORT AND PERIOD COVERED
		14. SPONSORING AGENCY CODE EPA/600/12
15. SUPPLEMENTARY NOTES <i>Hazardous Waste Engineering Research Laboratory</i>		
16. ABSTRACT Audits are an important and Integral part of the EPA HWERL Quality Assurance Program. As part of this overall QA Program, audits are used to determine contractor compliance with quality assurance plans and to assess the overall quality of data collected during data gathering or data generation activities. Additionally, audits are useful in evaluating the procedures used in collecting and analyzing samples, in all facets of data quality, and in management of the activity. Often, an audit of a sampling or analytical activity will reveal a problem which otherwise may have gone undetected until the end of the project. In such cases, on-site Corrective Action Recommendations are made. Four different types of audits are performed under the EPA HWERL QA Program: Management Systems Audits (MSA), Technical Systems Audits (TSA), Performance Evaluation Audits (PEA), and Audits of Data Quality (ADQ). Such audits of HWERL projects are conducted by the Quality Assurance Officer or a designated representative. Each type of audit has established Standard Operating Procedures and has a well-defined direction in evaluating a particular aspect of field and/or laboratory operations.		
17. KEY WORDS AND DOCUMENT ANALYSIS		
a. DESCRIPTORS	b. IDENTIFIERS/OPEN ENDED TERMS	c. COSATI Field/Group
18. DISTRIBUTION STATEMENT RELEASE TO PUBLIC	19. SECURITY CLASS (This Report) UNCLASSIFIED	21. NO. OF PAGES 14
	20. SECURITY CLASS (This page) UNCLASSIFIED	22. PRICE A03 12.95

NOTICE

This document has been reviewed in accordance with U.S. Environmental Protection Agency policy and approved for publication. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

**LABORATORY AND FIELD AUDITS AS PART OF THE EPA
HAZARDOUS WASTE ENGINEERING RESEARCH LABORATORY (HWERL)
QUALITY ASSURANCE PROGRAM**

W. Burton Blackburn, Staff Scientist, S-CUBED Division of Maxwell Laboratories, La Jolla, California 92038-1620; Guy F. Simes, Quality Assurance Officer, Hazardous Waste Engineering Research Laboratory, U.S. Environmental Protection Agency, Cincinnati, Ohio 45268

ABSTRACT

Audits are an important and integral part of the EPA HWERL Quality Assurance Program. As part of this overall QA Program, audits are used to determine contractor compliance with quality assurance plans and to assess the overall quality of data collected during data gathering or data generation activities. Additionally, audits are useful in evaluating the procedures used in collecting and analyzing samples, in all facets of data quality, and in management of the activity. Often, an audit of a sampling or analytical activity will reveal a problem which otherwise may have gone undetected until the end of the project. In such cases, on-site Corrective Action Recommendations are made.

Four different types of audits are performed under the EPA HWERL QA Program: Management Systems Audits (MSA), Technical Systems Audits (TSA), Performance Evaluation Audits (PEA), and Audits of Data Quality (ADQ). Such audits of HWERL projects are conducted by the Quality Assurance Officer or a designated representative. Each type of audit has established Standard Operating Procedures and has a well-defined direction in evaluating a particular aspect of field and/or laboratory operations.

INTRODUCTION

Audits are an important and integral part of the EPA Hazardous Waste Engineering Research Laboratory (HWERL) Quality Assurance Program. As part of this overall QA Program, audits are used to determine the compliance of contractors, in-house groups, and academic groups with previously approved Quality Assurance Program and/or Project Plans. Also, audits can be implemented to assess the overall quality of data collected during data gathering or data generation activities, in evaluating sampling and analytical procedures, and assessing the management of an activity.

Four different types of audits are conducted under the HWERL QA Program:

- (1) *Technical Systems Audit (TSA)* - a qualitative on-site evaluation of all components of the measurement systems, including personnel.
- (2) *Performance Evaluation Audit (PEA)* - a quantitative evaluation of critical measurements through an organization's analysis of Performance Evaluation (PE) samples.
- (3) *Audit of Data Quality (ADQ)* - an on-site assessment of the methods used to collect, interpret, and report the information used to characterize data quality.
- (4) *Management Systems Audit (MSA)* - an on-site evaluation of an organization's quality assurance management system.

In general, audits of HWERL projects are performed by the Quality Assurance Officer (QAO), or by a designated representative.

AUDIT DESCRIPTION AND PROCEDURES

Technical Systems Audit

The Technical Systems Audit (TSA) is one of the most utilized types of audit of the four types of HWERL audits. All aspects of sampling or data generation can be evaluated and the TSA may be project-specific or organization-specific. The TSA is particularly valuable in that it can be quickly implemented and completed, thus identifying potential problems and recommending corrective action while the subject project is still in progress. The TSA is conducted by one or two scientists or engineers, depending upon the nature of the project. These reviewers are generally chosen on a project-specific basis, based upon a combination of their quality assurance and related technical expertise. The QA Project Plan provides the basis for the audit, which generally takes one to two days to complete.

Some questions which may be of relevance to a TSA include:

- Is the project adequately staffed with personnel of relevant background to accomplish the objectives of the project? Is project organization and management sufficient to meet these same objectives?

- Does the organization devote sufficient resources and personnel (i.e., a Quality Assurance Officer) to an established Quality Assurance Program?
- Is the equipment used on the project being used for the purpose for which it was intended and is it being used properly?
- Are proper chain-of-custody and sample handling procedures being followed?
- Are personnel involved with the project knowledgeable, properly trained, and adequately supervised?
- Are the facilities being used sufficient to meet the needs of the project?
- Are sampling and analytical equipment being maintained properly, calibrated properly, and used in an appropriate manner?
- Are quality assurance and quality control procedures outlined by the organization in such documents as Work Plans and Quality Assurance Project Plans being followed according to planned procedures?
- Do standard operating procedures exist and are they up to date and complete?
- Do data validation procedures exist and is there sufficient review of data to minimize reporting of calculation errors?
- Is documentation of sampling and analytical procedures, data, QA/QC information, and corrective action adequate and well organized?

The audit proceeds in five phases:

- (1) A pre-visit planning phase is begun where the reviewers familiarize themselves with relevant documents (i.e., QA Project Plan) and make contact with on-site project management. A *Pre-Visit Worksheet* is sent to project

management, which is returned to the reviewers prior to the site visit. This worksheet provides the reviewers with current information regarding project organization, personnel, and equipment, as well as any changes to procedures given in the QA Project Plan.

- (2) The site visit begins with an initial meeting conducted by the reviewers and attended by key project personnel. Review procedures and objectives are discussed and an agenda is agreed upon. Following this discussion, the QA Project Plan is examined and questions or clarifications needed by the reviewers are addressed.
- (3) A facilities tour is conducted where project-related measurement equipment is viewed and responsible analysts are interviewed. In the case of a sampling effort review, sampling equipment and locations are seen. If possible, actual sampling and analytical work in progress is observed.
- (4) A review of documentation and data handling procedures is conducted. Usually, this is accomplished by selecting one or more samples at random and tracing their progress through sampling and analytical procedures and up to final data reporting.
- (5) Following an adjournment where the reviewers assimilate notes and observations, a debriefing and summary meeting is held. The reviewers discuss concerns and rank them in order of importance (i.e., critical, major, and minor). Project personnel are encouraged to engage in a constructive discussion with the reviewers and offer clarifications or additional information to the reviewers in response to the noted concerns. In concluding this meeting, and in consideration of discussions with project personnel, Corrective Action Recommendations (CAR) may be made. These are documented, on site, on a CAR Form (Figure 1). The HWERL Technical Project Officer receives this form within three days and is responsible for implementation and follow-up of any identified corrective action.

CORRECTIVE ACTION RECOMMENDATION (CAR) FORM FOR HWERL

Project Category: _____

QA I.D. No.: _____

Organization Reviewed: _____

Project Title: _____

Reviewer: _____ Affiliation: _____

Affiliation: _____

Review Type: _____ On-Bite Location: _____

On-Site Location: _____

Rating: _____ Technical PO: _____

Technical PO: _____

I. Date Problem Identified: _____

Problem serious enough that Part II must be completed by the HWERL technical project officer and submitted to the HWERL QA Officer? Yes _____ No _____

Nature of Problem:

Recommended Action:

Corrective Action Recommendation Form (Part I) has been reviewed by the organization's on-site representative:

Signature: _____ Date: _____
(Organization's On-Site Representative)

II. **Date Corrective Action Taken:**

Summary of Corrective Action:

QA Activity Implemented to Prevent Future Occurrences:

Effectiveness of Corrective Action:

Signature (HWERL technical PO): _____ Date: _____

HVERL (CAR)
(April 1957)

Figure 1. Corrective Action Recommendation (CAR) Form

Within one week following the on-site portion of the TSA, the reviewing group submits to the reviewed group a Draft TSA Summary Report detailing the positive aspects of the review, any concerns ranked by order of importance, and any corrective action recommendations, along with an audit rating (see Table 1). The reviewed group is allowed one week to read and respond to the TSA Summary Report. This response is included with the Final TSA Summary Report, which is then forwarded to the HWERL Technical Project Officer with a copy to the HWERL QAO. An important aspect of the HWERL TSA procedure is that the review is conducted, corrective action recommendations made on site via the CAR Form, and a report submitted to the HWERL Technical Project Officer in about three weeks. This timeliness allows for prompt resolution of any problems which may be present and gives the Technical Project Officer an immediate assessment of the quality of sampling and analytical activities associated with the subject project.

Performance Evaluation Audit

A Performance Evaluation Audit (PEA) is a quantitative evaluation of measurement systems. Usually, only the most critical measurements, as designated in the QA Project Plan, are evaluated. The PEA involves measurement or analysis of a reference material having associated with it a known value or composition. The value or composition of the reference material is certified, or at least verified, prior to use. The USEPA Environmental Monitoring and Support Laboratory in Cincinnati is active in preparation and certification of these materials.

Among the questions that may be determined from a PEA are:

- What is the bias and precision of the measurement system at the time of the audit?
- Under the ideal conditions presented in analysis of a performance evaluation sample, are the results generated by a given instrument and from a given method under control?
- If the results of previous audits are available, has data quality significantly changed?

Ideally, the performance evaluation sample should be submitted as a blind sample so that it receives treatment similar to other routine samples. The sample may be analyzed with an audit team present so that the actual

procedures used and the abilities of specific project personnel can be evaluated. The PEA is conducted as follows:

- (1) Submission of performance evaluation sample to the laboratory.
- (2) Results are returned to HWERL and subjected to a statistical analysis involving between-laboratory analysis. Results are considered acceptable if they are within defined limits (see Table 2).
- (3) If results are rated *Conditionally Acceptable* or *Not Acceptable*, corrective action is required of the subject laboratory. Such corrective action must be documented and submitted to the HWERL Project Officer and QAO for approval.
- (4) HWERL then approves the corrective action or makes further recommendations.

A PEA does not provide any information on overall project documentation or implementation of quality assurance because it is very narrow in scope. It can be very complimentary to a TSA because it provides quantitative data to supplement the qualitative data generated during the TSA.

Audit of Data Quality

Due to several major weaknesses observed in the field application of Audits of Data Quality (ADQ), HWERL has not undertaken such audits during FY86 and FY87. Instead, HWERL is involved in development of a different strategy for ADQs. The positive, comprehensive approach developed by HWERL to conduct Audits of Data Quality (ADQ) is a structured two-tiered approach. The first tier consists of a multipart questionnaire and rating scheme that enables the qualitative assessment of the sufficiency of verifiable documentation of data and their associated data quality indicators (e.g., precision, accuracy, representativeness, completeness, comparability, limits of detectability). The second tier consists of a two-part questionnaire and rating scheme that enables quantitative evaluation of data quality and end-user data acceptability. The HWERL ADQ approach combines many of the advantages of other approaches, including:

- The use of three-valued logic (*Yes/no/not applicable*), to minimize subjectivity.
- The use of weighted ratings, to emphasize the most critical evaluators of data quality.
- well-defined point-scoring and rating schemes, to provide unambiguous and comparable audit results.
- Well-defined acceptance criteria, to establish clear reference points from which corrective action decisions or other administrative judgment calls can be made.
- Independent rating of typical subsections of the questionnaires, to enable detailed evaluation of project strengths and localized identification of problem areas.

Management Systems Audit

The Management Systems Audit (MSA) is not presently performed by HWERL; rather, it has historically been performed by either EPA's Quality Assurance Management Staff (QAMS) or Office of Environmental Engineering and Technology Demonstration (OEETD). The audit is to investigate HWERL QA procedures. An evaluation of the adequacy of the internal management systems necessary for the successful implementation of a quality assurance program is made. Since HWERL does not conduct these audits, detailed procedures are not described here.

RESULTS OF FY86 AND FY87 AUDITS

Following the completion of a TSA or PEA, an evaluation rating will be assigned. These ratings and the corrective actions required are given in Tables 1 and 2. It should be noted that HWERL policy dictates that measurement work should not proceed for projects given *Conditionally Acceptable* or *Not Acceptable* review or audit ratings. Only deficient measurement systems may be stopped where other measurement systems within a project are acceptable. Also, work may not be stopped at all if data quality would further suffer through this action and corrective action can be quickly and easily implemented.

Table 3 gives a summary of the types of audits conducted in FY86 and FY87 and the ratings given.

Table 1. HWERL Rating System for TSA

<u>Rating</u>	<u>Explanation/Action Required by the Technical Project Officer</u>	<u>Status of Measurements</u>
Acceptable	None	Work Proceeds
Acceptable with Qualifications	Minor deficiencies are revealed by the audit. Minimum criteria are satisfied and good data quality seems likely; qualifications on the possible limitations of the data are noted and some corrective actions may be recommended. The recommendations may be implemented at the Technical Project Officer's discretion.	Work Proceeds
Conditionally Acceptable	Major concerns are identified by the audit. Corrective action* is required by the Technical Project Officer to ensure quality results	Measurement work should not proceed for Category I or II Projects.**
Not Acceptable	Critical deficiencies are revealed by the audit that require the Technical Project Officer to take substantial corrective action* before measurement work proceeds.	Measurement work should not proceed until deficiencies are resolved.

* Part II of the Corrective Action Recommendation Form is to be used by the Technical Project Officer in documenting the resolution of cited deficiencies.

** Category III and IV Projects: Measurement work may proceed, but the deficiencies that were cited in the audit report must be resolved within thirty (30) days. If the deficiencies are not resolved during the 30-day grace period, then the measurement work should not proceed.

Table 2. HWERL Rating System for PEA

<u>Rating</u>	<u>Explanation/Action Required by Technical Project Officer</u>
Acceptable	All critical measurements are within a 99 percent confidence interval calculated from available performance evaluation data of EPA and State laboratories.
Conditionally Acceptable	Eighty percent or more of the critical measurements are within the above-cited 99 percent confidence interval. Those critical measurements which are outside of the confidence interval are identified for corrective action at the direction of the Technical Project Officer.
Not Acceptable	Less than 80 percent of the critical measurements are within the above-cited 99 percent confidence interval. The project, itself, is flagged and those critical measurements which are outside of the confidence interval are identified for corrective action at the direction of the Technical Project Officer.

Note: Measurements which are not critical to meeting the project's QA objectives and which are not within the 99 percent confidence interval are flagged, but do not affect the rating.

Table 3. HWERL Audits in FY86 and FY87¹

<u>Audit Type</u>	<u>Number Conducted</u>	<u>Rating²</u>			
		<u>A</u>	<u>A/Q</u>	<u>C/A</u>	<u>N/A</u>
TSA	14	4	3	5	2
PEA	30	7	-	21	2

¹Through June 1987

² A - Acceptable
A/Q - Acceptable with Qualifications
C/A - Conditionally Acceptable
N/A - Not Acceptable